REMARKS

Claims 1-15 are currently pending in the application. By this amendment, claim 1 is amended for the Examiner's consideration. The foregoing separate sheets marked as "Listing of Claims" show all the claims in the application, with an indication of the current status of each.

The Examiner has rejected claims 1, 3-5, 7, and 11-14 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,979,304 to Nijenbanning et al. ("Nijenbanning") in view of U.S. Patent No. 6,462,431 to Woo.

The Examiner makes the following statements in response to the applicant's prior arguments:

Applicant's argument:

> "It cannot be argued that there is 'common sense' in reaching to the prior art of bicycle theft prevention techniques to find a teaching that, at a high level of abstraction, happens to characterize user monitoring of "locking" of a prosthetic device. This reaching to an unrelated prior art, without any supportive reasoning, simply confirms the hindsight bias of the Examiner's obviousness determination." (Emphasis supplied; Applicant's 08/06/2009 response, page 8)

Examiner's Response:

> "However, the Nijenbanning and Woo references are analogous pieces of art because they both disclose the use of remote controlled locking devices. When using a remote controlled device, it is beneficial to have an alert to the user of the change in state of the device being controlled by the remote in order to ensure the user knows the signal has reached the device and both the remote and the device are functional." (Office Action mailed 11/24/2009, page 2)

It is requested that the Examiner reconsider, in view of the level of abstraction at which the Nijenbanning and Woo references may be viewed as analogous. Nijenbanning is clearly related to the art of the present invention, providing a hinge device that automatically unlocks to allow natural swinging of the lower part of the leg when weight has been transferred to the opposite leg. This is related to the

present invention because both Nijenbanning and the present invention involve prosthetic devices and, more particularly, prosthetic devices for the leg. One skilled in the art of such prosthetic devices would reasonably be presumed to know of the Nijenbanning reference.

On the other hand, one skilled in the art would not find in Nijenbanning a description or suggestion pertaining to the aspects of the present invention at issue, namely, detecting the locking state and alerting the user to the locking state. It is reasonably evident why this is so. Nijenbanning discloses a novel mechanism for stabilizing the knee joint only when it is necessary to place weight on the leg, allowing the leg to swing normally when weight is on the other leg. This is an improvement on the prior art, which required walking with a stiff leg and unlocking the prosthesis when sitting down.

It is to be noted that aspects of this improvement were already known in the art, as Nijenbanning pointed out in the background section. It was old in the art to unlock the joint at the start of the swinging stage (col. 1, lines 50-51). Further, the prior art disclosed locking the joint upon detection of stress, for example, upon the heel (col. 1, lines 53-55). However, this technique is disadvantageous because the joint is unlocked in the absence of stress upon the heel, leaving the user vulnerable to collapse and injury if there is stress from another quarter, such as the front of the user's foot (col. 1, lines 62-65). Other prior art disclosed changing the state of the hinge based on the presence of axial force on the hinge (col. 2, lines 6-8), or turning the foot relative to the leg (col.2, lines 13-14), although this requires the user to be prepared to turn the foot at every step (col. 2, lines 20-21).

Nijenbanning claims as novel a hinge release and locking technique that is automatic during walking, invoked by gravity in coordination with the movement of the leg while the user is walking. The Examiner does not, of course, rely upon this feature of the Nijenbanning disclosure. Indeed, the only features relied upon are those which are admitted to be old in the art, even by Nijenbanning. Yet, as with Nijenbanning, it is necessary to include these features in the claim because they

provide the context for the invention. These contextual and non-novel aspects are an orthopedic aid, used for walking and providing a support function, comprising two parts movable relative to one another and a device for locking the two parts relative to one another. These features do no more than describe the context of the invention.

In addition to the inventive gravity operated automatic mechanism for coordinating locking and unlocking with walking, Nijenbanning describes a manual override allowing the user to lock or unlock the hinge (col. 6, lines 31-46) with a control (item 20 in Fig. 1). Properly understood, this use of a manual control provides the user with the ability to operate the hinge control when the user "wants to be able to influence whether or not the hinge ... is locked" (col. 6, lines 32-33). It is a simple control, not dependent upon the state of the system. If the user wants to step backward, for example, the hinge can be locked (col. 6, lines 42-44); if the user wants to sit down, the hinge can be unlocked (col. 6, lines 39-42).

This detail is reviewed to make it clear that Nijenbanning provides no suggestion whatsoever regarding detection of the state of the device, or alerting the user to that state. The Nijenbanning mechanism is automatic, with no need to alert the user. Indeed, avoiding any need to alert the user is a primary advantage to Nijenbanning's automatic mechanism. On skilled in the art would have no motivation to modify Nijenbanning's automatic mechanism in any manner that would suggest the present invention. It is questionable whether the present invention would be operable in the context of an automatic mechanism. It is worth emphasizing that Nijenbanning teaches in the opposite direction, because in reviewing the prior art Nijenbanning found that having to alert the user (e.g. with regard to turning of the foot, col. 2, lines 19-21) was a circumstance to be avoided. The point of the automatic mechanism is precisely to avoid any need to alert the user.

Nor does the option for manual control (col. 6, lines 31-46) provide any suggestion useful to one skilled in the art. This control is initiated by the user, not in the sense of being "alert" to an external circumstance but rather as a means for deliberate action by user, such as walking backward or sitting down. In such

circumstances the automatic mechanism is not applicable and the intentions of the user are being implemented. Again, one skilled in the art would find no motivation to seek a mechanism for alerting the user to the locked or unlocked state of the prosthetic. No such motivation is present in Nijenbanning, or suggested by Nijenbanning.

The Examiner acknowledges that "Nijenbanning fails to disclose a means for detecting the locking state and a means for alerting a user of the locking state." Then the Examiner uses a creative argument in an attempt to show how and why the manual override mechanism could be modified so as to employ the present invention. There is a cable running from the override switch (20) to the hinge. The Examiner speculates that this cable is subject to "tangling ... during usage", and that Woo's wireless controller could be used to detect the locking state, send an LED signal to the user and thereby prevent further injury.

This logic is overly creative. There is no indication in Nijenbanning that the cable could become tangled. It is a cable, not a loose wire. These kinds of cables are well known in the prosthetic arts, and are stiff in order to be operable for both pushing and pulling. Indeed, it is evident from Fig. 1 that the Nijenbanning mechanism operates in just this way. It is evident that the Examiner has attempted to apply the present invention to the circumstances of Nijenbanning. This is exactly the reverse of the question posed to one skilled in the art. The Examiner has shown how difficult it is to modify Nijenbanning to make use of the present invention. *A fortiori*, it is unlikely that one skilled in the art would have made this leap, with or without the Woo reference.

The Examiner has been further creative in asserting that one skilled in the art would have connected the Woo reference to Nijenbanning in the first place. Woo is responsive to the problem of disuse of locks on bicycles, mainly because of the inconvenience to users of applying the lock. These kinds of locks have no similarity to the prosthetic "locks" described in Nijenbanning. The very concept of "lock" in Woo is unconnected to the present invention. The Woo lock is for immobilizing a

bicycle so that it cannot be stolen by a thief. The Woo lock functions by making an attachment between the bicycle and a relatively immovable object, such as a street light pole bolted or cemented to the pavement.

It is only at a very high level of abstraction that any relevant connection can be found in the Woo lock. The word "immobilize" can be applied to two parts which are moveable with respect to one another. But one skilled in the art would not associate the pairs that the Examiner has put together. It is one thing to immobilize two parts coupled by a hinge in a prosthetic device. It is quite another sense of the term to immobilize a bicycle by attaching it to a street light pole. One skilled in the art would not use these terms interchangeably. Furthermore, the locking mechanism in Woo, and the remote controller in Woo, have a completely different sense of the terms "lock" and "unlock" than these terms as they are used in the present invention and in Nijenbanning, except at a very high level of abstraction. The two parts in a prosthetic device are operably connected. Not so with a bicycle and a light pole. Locking and unlocking this operable connection in a prosthetic device has an affect on the operability of the prosthetic device. Locking and unlocking the Woo device has a completely different sense. The bicycle and the light pole are "locked" in a proximity so that the bicycle cannot be easily separated from the light pole, which is fixed in a place known to the bicycle owner. When the Woo lock is released, the bicycle owner can be on his or her way. There is no connection to the operability of locked and unlocked states in a prosthetic device.

Even the control mechanism in Woo requires a leap of abstraction to relate to the present invention. In Woo, the lock can be operated remotely. The operation of the remote locking mechanism has nothing to do with the operability of the two parts locked together. With a prosthetic device the locked position allows the user to use the two parts as a load bearing prosthesis. When the Woo device is locked, the user may leave the scene. At a very abstract level, perhaps the user of the Woo device can shift the worry that the bicycle may be stolen to a state of confidence that the locked

device will prevent that eventuality, thus giving the locking mechanism a load bearing quality.

A detailed analysis of the signaling for operation of the remote controller in Woo does not overcome the difficulty of the high level of abstraction required to connect the Nejenbanning and Wood references. For example, the release of the locking state of the lock of Woo may be signaled by an alarm tone generating unit. The signal does not serve to secure safe operation of the device but merely indicates that the lock has been opened. Since Nijenbanning discloses a knee hinge which automatically unlocks and locks during each walking cycle an alarm signal which would be emitted, e.g. each time the hinge is locked in the extended position, applying Woo means that the alarm would occur during each walking cycle. This would be highly disturbing and distressing for the patient. There is no way of using the alarm tone in Woo for manual operation only, since Woo discloses a position detector of the locking means for generating the alarm tone signal. Since the locking means in Nijenbanning et al. is the same for the automatic locking / unlocking and manual operation, the alarm tone would be generated for each locking or unlocking regardless whether the locking or unlocking has been performed automatically or manually operated.

Consequently, for all the foregoing reasons, it is submitted that one skilled in the art would not be motivated to seek practical application at the level of abstraction required to connect Nejenbanning and Woo. It is respectfully requested that this ground of rejection be withdrawn. It is further submitted that no *prima facie* case has been established.

For the completeness of the record, the arguments made in the prior response are repeated for the Examiner's review in light of the foregoing.

As noted by the Examiner, Nijenbanning fails to disclose a means for detecting the locking state and a means for alerting a user of the locking state. However, the Examiner fails to note that Nijenbanning does not even disclose a predicate for one skilled in the art to look for the locking detection and alerting

limitations of the present invention. Nijenbanning is directed toward an automatic locking and unlocking hinge mechanism, with a manual override for use by the user for such situations as sitting down and taking a step backward. There is no suggestion in Nijenbanning of a situation where the user would be concerned that the hinge mechanism is not locked when the user places weight upon the leg, for example. Indeed, the design disclosed in Nijenbanning is such that "the position of the locking element is unambiguously defined at all times" (col. 3, lines 38-39) and "the locking element has two stable positions" (col. 3, lines 40-41). Depending on the position of the hinge, the locking element will be moved into either the first position or the second position (col. 3, lines 41-44). The disclosure further provides that

> "When the hinge 1 is locked, ... a user can safely place weight on the leg 2 in the knowledge that the knee is locked." (col. 6, lines 16-19)

The Nijenbanning hinge device is so designed that it relies upon the force of gravity during the user's walking motion to shift the device between the locked and the unlocked positions. In one embodiment the mechanism for accomplishing this two-state condition is comprised of "a cylinder or ball 200 able to execute a rolling or sliding back-and-forth movement between two stable positions" (col. 7, lines 36-39). As the leg is swung backward during walking "gravity forces the cylinder/ball into its other stable position, as a result of which the upper and lower parts are unlocked" (col. 7, lines 45-47). In another embodiment the mechanism is "a bi-stable element 114" which responds to changes in its center of gravity while the user is walking so that the element is "flipped over" to a first locked position and as the leg swings backward the element "will flip over into its second position" (col. 8, lines 18-30). Importantly, "free oscillation of the element 114 will not be possible with this embodiment" (col. 8, lines 32-33).

With regard to the manual operation of the displacement mechanism, Nijenbanning describes a disc rotation mechanism, where the axis of rotation of the

disc is coincident with the axis of rotation of the locking element (col. 4, lines 41-42), such that

> "By rotating the disc in a first direction the locking element can be so moved, with the aid of the stops, that it always releases the hinge. By rotating the disc in the opposite direction the locking element is so manipulated by the stops that it locks the hinge at all times" (emphasis supplied; col. 4, lines 46-51).

Thus one skilled in the art would not be motivated from the Nijenbanning disclosure to consider a further mechanism for detecting the locked or unlocked state of the Nijenbanning hinge and alerting the user to the condition. Nowhere in Nijenbanning is there any suggestion of a need for entertaining such a further mechanism. Consequently, it is evident that the suggestion and motivation for the addition of such a feature to Nijenbanning are provided by impermissible hindsight, based upon the disclosures of the present invention, which would not have been available to one skilled in the art. The Examiner has not provided evidence to the contrary, nor does the Examiner's argument – which is very brief and simply states a conclusion – support a contrary inference.

Furthermore, the inference of impermissible hindsight bias is confirmed by the Examiner's use of the distant art of bicycles to provide the required teaching. It is difficult to avoid the conclusion that the Examiner has simply pieced together elements of prior art whose connection is motivated not by the prior art but by the claimed invention itself. This is classic hindsight bias.

The Woo prior art is about bicycles. In the first place, however, Woo's teaching about detection and alerting could not be permissibly applied to Nijenbanning because there is no suggestion or motivation in Nijenbanning for doing so. It should be noted that the recent case of *KSR v. Teleflex*, 550 U.S. 398 (2007), while finding that a rigid reliance on the TSM standard went too far, emphasizes that hindsight bias must be addressed in the obviousness analysis.

> "The Court of Appeals, finally, drew the wrong conclusion from the risk of courts and patent examiners falling prey to hindsight bias. A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning. See *Graham*,

> 383 U. S., at 36 (warning against a "temptation to read into the prior art the teachings of the invention in issue" and instructing courts to " 'guard against slipping into the use of hindsight' " (quoting *Monroe Auto Equipment Co.* v. *Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964)). Rigid preventative rules that deny factfinders recourse to common sense, however, are neither necessary under our case law nor consistent with it." *KSR*, at slip p.17.

It cannot be argued that there is "common sense" in reaching to the prior art of bicycle theft prevention techniques to find a teaching that, at a high level of abstraction, happens to characterize user monitoring of "locking" of a prosthetic device. This reaching to an unrelated prior art, without any supportive reasoning, simply confirms the hindsight bias of the Examiner's obviousness determination.

A *prima facie* case of obviousness cannot be established by conclusory statements combining prior art teachings, but must provide a reasoned analysis, in the absence of which it is proper to infer improper hindsight bias.

> "We have noted that evidence of a suggestion, teaching, or motivation to combine may flow from the prior art references themselves, the knowledge of one of ordinary skill in the art, or, in some cases, from the nature of the problem to be solved, [citations omitted] although "the suggestion more often comes from the teachings of the pertinent references," [citation omitted]. The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular. [citation omitted]. Broad conclusory statements regarding the teaching of multiple references, standing alone, are not "evidence." [citations omitted]. In addition to demonstrating the propriety of an obviousness analysis, particular factual findings regarding the suggestion, teaching, or motivation to combine serve a number of important purposes, including: (1) clear explication of the position adopted by the Examiner and the Board; (2) identification of the factual disputes, if any, between the applicant and the Board; and (3) facilitation of review on appeal." (emphasis supplied; *In re Dembiczak*, 175 F.3d 994 (CAFC 1999)).

The reasoning of *Dembiczak* has been approved by the CAFC in decisions subsequent to the Supreme Court's *KSR* opinion. See, for example, the following emphasis on the importance of supporting reasoning with factual findings:

> "The underlying factual inquiries in an obviousness analysis include: "(1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness." In re Dembiczak, 175 F.3d

> 994, 998 (Fed.Cir.1999)." (Daiichi Sankyo v. Apotex, 501 F.3d 1254, 1256 (CAFC 2007).

Further, the requirement of reasoned analysis is affirmed in *KSR*:

> "To facilitate review, this analysis should be made explicit. See *In re Kahn*, 441 F. 3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.")" *KSR* at slip p. 14.

The full context of the *Kahn* language favorably cited by the Supreme Court provides further emphasis on the importance of avoiding hindsight bias by including obviousness reasoning on the record in concrete and specific detail rather than conclusory statements:

> "The motivation-suggestion-teaching test picks up where the analogous art test leaves off and informs the Graham analysis. To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references, the Board must provide some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct. The requirement of such an explanation is consistent with governing obviousness law, see § 103(a); *Graham*, 383 U.S. at 35, 86 S.Ct. 684; *Dann*, 425 U.S. at 227-29, 96 S.Ct. 1393, and helps ensure predictable patentability determinations.
>
> "A suggestion, teaching, or motivation to combine the relevant prior art teachings does not have to be found explicitly in the prior art,
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> > 'as the teaching, motivation, or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references.... The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.' *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir.2000) (internal citations omitted).
>
> "However, rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. See *Lee*, 277 F.3d at 1343-46; *Rouffet*, 149 F.3d at 1355-59. This requirement is as much rooted in the Administrative Procedure Act, which ensures due process and nonarbitrary decision making, as it is in § 103. See id. at 1344-45. In considering motivation in the obviousness analysis, the problem examined is not the specific problem solved by the invention but the general problem

that confronted the inventor before the invention was made." (emphasis supplied; *In re Kahn*, 441 F.3d 977 (CAFC 2006), 987-988.

The Patent and Trademark Office guidelines published at 72 Fed. Reg. 57526 (October 10, 2007), at pp. 57529-34, provide for alternative analyses to demonstrate obviousness, but the Examiner has not used any of them. These PTO guidelines specifically contemplate that the Examiner would have "established the *Graham* factual findings and concluded that the claimed invention would have been obvious" in making a *prima facie* case. Only when this has been done does the burden shift to the applicant to "show that the Office has erred in these findings" (emphasis supplied; 72 Fed. Reg. at 57534). It is clear that the "factual findings" and the "conclusions" drawn from these findings are separate requirements. In the present case there have been no findings, only bare conclusions.

It is apparent that the Examiner has fallen victim to hindsight bias by reading into Nijenbanning a suggestion and motivation that is found not in Nijenbanning but rather in the present invention. Use of the Woo reference confirms this conclusion. One skilled in the art of prosthetics would not go far afield to the art of bicycles. Further, the device described in Woo is for using a remote control to facilitate the locking and unlocking of a bicycle theft prevention device. It is not apparent how the teachings of the Woo device could be applied to a completely different design. In Woo, there is no hinge for joining two members. While the terms "locked" and "unlocked" are used in both Woo and Nijenbanning, one skilled in the art of prosthetics would find no structures in Woo helpful in designing or implementing a lock status detection and alert mechanism for the hinge and prosthetic device described in Nijenbanning, even assuming a suggestion and motivation for such a status detection and alert mechanism were present in Nijenbanning. And it is clear from what has been said above that no such suggestion or motivation can be found in Nijenbanning.

Consequently, it is submitted that the Examiner has failed to make a *prima facie* showing of obviousness, and has instead relied upon the bias of hindsight from

knowledge of the present invention. It is therefore submitted that the §103 ground of rejection as to claim 1 is overcome, and should be withdrawn. It is further submitted that claim 1 is in allowable form over the prior art, and therefore that all the remaining claims 3-15 are also allowable because they depend from allowable claim 1.

The Examiner has rejected claims 6, 8 and 9 under 35 U.S.C. §103(a) as being unpatentable over Nijenbanning and Woo in view of U.S. Patent No. 6,184,797 to Stark et al. ("Stark") and further in view of U.S. Patent No. 7,235,058 to Doty. The Examiner has rejected claim 10 under 35 U.S.C. §103(a) as being unpatentable over Nijenbanning, Woo, Stark and Doty as applied to claims 1, 6 and 8, and further in view of U.S. Patent Application Publication No. 2002/0183673 to Naft et al. ("Naft"). The Examiner has rejected claim 15 under 35 U.S.C. §103(a) as being unpatentable over Nijenbanning and Woo as applied to claims 1, 11 and 13, and further in view of Stark. These additional grounds of rejection are moot in view of the foregoing discussion of the inadequacies of the Nujenbanning and Woo references, and the consequent allowability of claim 1 and all claims dependent from claim 1.

However, it should be noted that Doty also discloses a lockable hinge which for a normal operation provides locking and unlocking during a walking cycle. There is a possibility to manually operate the locking element so as to permanently lock or unlock the hinge. There is no disclosure for or a hint to a detection device for the position of the locking element and for a signaling device. Therefore, the above arguments regarding Nijenbanning also apply for Doty. Naft also discloses a hinge which may be locked and unlocked during a walking cycle. Locking and unlocking is controlled by sensor 114, e.g. arranged in a foot plate for sensing patient's weight load on the leg/foot during walking. There is no disclosure or a hint of a detection device and a signaling device according to the present invention. Stark has been intensely discussed in the responses to previous Office Actions. There is not disclosed in Stark an orthopedic aid for walking on but instead a training device used during sitting.

With particular reference to claim 10, the claim does not consist only of the idea to have a low actuating force. The low actuating force has its meaning in combination with the slight play of the joint in the extended position. This makes it possible to unlock the joint in the extended position if no torque acts on the joint. If, however, a torque is exerted on the joint the actuating arrangement will not be successful to unlock the joint, thereby providing for an increased safety for the user against falling because of buckling of the orthopedic aid (see p. 1, lines 38-39; p. 4, lines 6-27). This aspect of the invention cannot be shown from Stark in view of Naft because Naft does not show any play in a lockable position of the joint allowing an unlocking with a small unlocking force.

It is submitted that these considerations have not been addressed by the Examiner, with regard to claim 10, and that claim 10 is therefore allowable in any event.

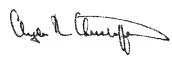
However, in order to move this prosecution forward, an amendment has been made to claim 1. It is requested that the Examiner entertain a telephone interview with the undersigned to further consider how this case may be put in condition for allowance.

In view of the foregoing, it is requested that the application be reconsidered, that claims 1 and 3-15 be allowed, and that the application be passed to issue.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at 703-787-9400 (fax: 703-787-7557; email: clyde@wcc-ip.com) to discuss any other changes deemed necessary in a telephonic or personal interview.

If a further extension of time is required for this response to be considered as being timely filed, a conditional petition is hereby made for such extension of time. Please charge any deficiencies in fees and credit any overpayment of fees to Attorney's Deposit Account No. 50-2041.

Respectfully submitted,



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